K093368

JAN 27 2010

510(k) Summary

Date prepared:			
Applicant:	Global Marketing Partners dba Gymmax USA 3488 Rockhaven Circle Atlanta, GA 30324		
Contact person:	Nicolaas C. Besseling, Consultant BesTech Consulting Services 28711 Jaeger Drive Laguna Niguel, CA 92677 949.466.7472 bestechconsulting@cox.net		
Trade name:	Butterfly Toner		
Common name:	Muscle stimulator	Class:	2
Classification name:	Powered muscle stimulator	Product code:	NGX
Predicate device:	Slendertone 512, K010335		
Device description:	The Butterfly Toner is a single channel, battery operated muscle stimulation system for exercising the abdominal muscles. The Butterfly Toner has two electrodes fixed at a distance of 28 mm.		
Intended use:	The Butterfly Toner is indicated for the improvement of abdominal muscle tone, strengthening of the abdominal muscles, and development of a firmer abdomen.		
Technological characteristics:	The device has an electronic stimulation controller that connects directly with "press-studs" to the electrodes, thus avoiding the need for an electrode cable. The device offers a selection of programs and voltages to suit individual needs. The user has no access to the wiring or the connectors, and cannot change the programming of the units.		
Non-clinical tests submitted or relied upon:	Waveforms as provided		
Clinical tests submitted or relied upon:	None.		
Substantial equivalence conclusion:	The Butterfly Toner is substantially equivalent to the Slendertone 512 because they use equivalent technology and have the same intended use.		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Globus Marketing Partners dbs Gymmax USA
% BesTech Consulting Services
Mr. Nicolaas C. Besseling
28711 Jaeger Drive
Laguna Niguel, California 92677

JAN 27 2010

Re: K093368
Trade/Device Name: Butterfly Toner
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: NGX
Dated: October 23, 2009
Received: October 29, 2009

Dear Mr. Besseling:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for use

510(k) number (if known:

Device name: Butterfly Toner

Indications for use: The Butterfly Toner is indicated for the improvement of abdominal muscle tone, strengthening of the abdominal muscles, and development of a firmer abdomen.

Prescription use( ) and/or Over-The-Counter use (√)
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

FOR M. MELKERSON

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093368